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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,904	11/27/2000	Michael H. Julius	47841/00063	4246

27871 7590 04/08/2003

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CANADA

EXAMINER

TELLER, ROY R

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 04/08/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/721,904

Applicant(s)

JULIUS ET AL.

Examiner

Roy Teller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 159-227 is/are pending in the application.
- 4a) Of the above claim(s) 177, 178, 181-186, 190, 191 and 195-227 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 159-176, 179, 180, 187-189 and 192-194 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This office action is in response to Paper No: 11, received 3/14/03, in which applicant elected group I, claims 159-176, 179-180, 187-189, and 192-194 with traverse. Applicant added new claims 196-227 to be examined with the elected group I claims. The traverse to examine the new claims is acknowledged.

Claims 159-163, 166, 168-176, 179-180, 187-189, 192-194 and 196-227 will be examined in this office action.

Claims 165 and 167 are withdrawn due to non-elected inventions.

Claim Objections

Claims 200-202 are objected to for depending upon themselves. Appropriate correction is requested.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 163, 164, 166, 168-176, 179-180, 196, 197, 199-207, 210-213, 216-219, 222-223, and 226-227 are rejected under 35 U.S.C. 102(e) as being anticipated by Julius (USPN 6,093,693).

The applied reference has a common SEQ ID NO:4 with the instant application. Julius teaches a method of activating B cells in a mammal, by administering CD14, see abstract. Julius discloses SEQ ID NO: 4 which is a 100% query match with SEQ ID NO:4 of the instant application, see STIC search. Julius teaches that CD14 can be administered to an infant, by incorporating CD14 into infant formula, see abstract. Julius discloses CD14 protein purified from bovine colostral whey, see abstract. Julius teaches administration could be by any convenient means, see column 18, line 8.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 159-163, 168-169, 187-189, 192-194, 198, 208-209, 214-215, 220-221 and 224-225 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diamond (Proc. Natl. Acad. Sci., vol. 93, pp 5156-5160, May 1996) in view of Julius (USPN 6,093,693).

The claimed invention is drawn to a method of stimulating expression of defensin by administering a compound comprising soluble CD14 to epithelial cells of a mammal. The protein has an amino acid sequence of at least about 63%, 68%, 71%, 73%, 78% 83%, 88%, 93%, or 98% conserved in relation to SEQ ID NO:4.

Diamond teaches tracheal epithelial cells exposed to bacterial lipopolysaccharides express CD14, see abstract. Diamond discloses a widespread mechanism of host defense in the animal kingdom is the production of antibiotic peptides/ defensins, see page 5156, column 1, paragraph 2. Diamond teaches the soluble form of CD14 can mediate lipopolysaccharide-stimulated responses in epithelial cells, see page 5157, column 2, paragraph 4. Diamond discloses *in vivo* evidence for increased expression of B-defensin lingual antibiotic peptide in the squamous epithelium of the tongue, see page 5159, column 2, paragraph 2. Diamond does not teach a structure of CD14.

Julius teaches a method of activating B cells in a mammal, by administering CD14, see abstract. Julius discloses SEQ ID NO: 4 which is a 100% query match with SEQ ID NO:4 of the instant application, see STIC search. Julius teaches that CD14 can be administered to an infant, by incorporating CD14 into infant formula, see abstract. Julius discloses CD14 protein purified from bovine colostrum whey, see abstract.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have added the teachings of Diamond to protein of Julius in order to

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enhance expression of antibiotic peptides/ defensins because Diamond teaches that many mammalian epithelial cells have the capacity for analogous host defense responses.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703) 305-4243. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RT
1654
4/1/03

RT

Brenda Brumback
BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600